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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,274	12/19/2005	Toshihiko Kakiuchi	1110-0339PUS1	5695

2292 7590 06/01/2007

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EXAMINER	
HUANG, GIGI GEORGIANA	

ART UNIT	PAPER NUMBER
1609	

NOTIFICATION DATE	DELIVERY MODE
06/01/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/561,274	KAKIUCHI, TOSHIHIKO	
	Examiner	Art Unit	
	GiGi Huang	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/19/2005, 1/31/2006, 3/01/2006.

DETAILED ACTION

Status of Application

1. Claims 1-6 are present for examination at this time.

Information Disclosure Statement

2. The information disclosure statement filed December 19, 2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because JP-4-226915-A and JP-200-510006-A do not have any translations and in the information disclosure statement filed January 31, 2006, only the abstract of JP- 2001-122791-A has been considered as being the only part translated. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1- 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutic treatment, does not reasonably provide enablement for prophylactic prevention of varicose veins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to develop and use the invention commensurate in scope with these claims.

The claims are broadly drawn to prophylactic/prevention of varicose veins. The claims taken together with the specification imply 100% prevention and prophylactic prevention of varicose veins with the composition.

The state of the art utilizes exercise, compression therapy, sclerotherapy, laser surgeries, catheter-assisted procedures, vein stripping endoscopies, and phlebotomy to manage and improve the signs and symptoms of varicose veins but there are no treatments for prophylactic prevention (100%) for the condition (see Mayo Clinic sheets on varicose veins- Treatment and Prevention).

The condition is difficult to predict and it is unclear who will be affected and what degree leading to its unpredictability in the art. This requires those in the art to have a high level of skill especially for surgical procedures, as it is common that there is an inverse relationship between predictability and those skilled in the art.

Considering the state of the art as discussed by the references above, particularly with regards to treatment verses prophylactic prevention of varices and the high unpredictability in the art as evidenced therein, and the lack of guidance provided

in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 5 and 6 provides for the "use of eicosapentaenoic acid in the manufacture of" and "method for preventing and treating....by using eicosapentaenoic acid" but, since the claims does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 5 and 6 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United State

8. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Yazawa et al (EP 0,404,300).

Yazawa et al. teaches a phospholipid composition comprising eicosapentaenoic acid and a method of making.

Yazawa et al. teaches an EPA-containing phospholipid composition made by utilizing microorganisms to produce eicosapentaenoic acid (EPA) and several methods of fractionation to purify the EPA-containing phospholipids for formulation (Abstract, Page 2, lines 1-5).

The EPA-containing phospholipids can be used in many formulations, including foodstuffs, cosmetics, pharmaceuticals, agriculture, fishing, and chemical industries. Preferable formulation forms were capsules, granules, pills, suspensions, emulsions, powders, tablets, syrup, and injectable liquids with pharmaceutical or biological acceptable additives (Abstract, Page 2, lines 1-9, 27-38, 40-55, Page 3, lines 1-15, 34-60, Page 4, lines 1-12, 20-29).

The composition was also envisioned as a pharmaceutical treatment of disease (i.e. human, pets, animals), an animal feed, a health food, and a lipid metabolism modifier (supplement/health food) (Abstract, Page 2, lines 27-38, 40-55, Page 3, lines 1-15, 34-60, Page 4, lines 1-12, 20-29, Table 1, Page 6, Examples 2 and 3, lines 20-56, Claims 1 and 9).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

9. Claims 1-3 and 6 rejected under 35 U.S.C. 102(b) as being anticipated by Kiliaan et al. (WO 01/84961).

Kiliaan et al. teaches a composition comprised of long chain polyunsaturated fatty acids, preferably eicosapentaenoic acid, for use of vascular disorders.

Kiliaan et al. teaches the composition to have best results when EPA is mixed with docosahexaenoic acid (DHA) for the long chain polyunsaturated fatty acids. The composition can be a dietetic, pharmaceutical, and a nutritional preparation.

The product forms could be a liquid, powder, bar, cookie, sweet, concentrate, paste, sauce gel, emulsion, tablet, capsule for providing a daily dose either as a single or multiple dose form. The products would be packaged by methods know in the art to keep the products fresh for easy use, administration, and shelf life (Abstract, Page 5, lines 23-32, Page 6, lines 1-9, 24-28).

Examples of the compositions are taught including, capsules (EPA at 75 mg, Page 13, Example 1), pudding (EPA at 30mg, Page 13, Example 2), powdered concentrate for use inn drinks (EPA about 150mg, Page 14, Example 3), and muesli-bar/food (EPA about 60mg, Page 14 and 15, Example 5).

The uses for the compositions are for the treatment of vascular, cardio-and cerebrovascular disorders and a selected range of secondary problems. Specific cardiovascular problems that were addressed were thrombi, vascular accidents, atherosclerosis, and varicose veins/varices (Page 11, lines 28-30, Page 12, lines 9-14).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

10. Claims 1-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruzzese (U.S. Pat. # 5,776,978).

Bruzzese teaches a composition comprising EPA and/or DHA in their fatty acid, ester, and salts forms for use in the prevention and/or treatment of arthrosclerosis, nervous system, cardiovascular, skin, and malignant pathologies (Abstract, Col. 1, lines 5-22).

Bruzzese teaches compositions comprised of EPA esters or EPA ethylesters. Examples included DHA esters and ethylesters. Bruzzese teaches that it is understood that DHA and EPA in any of the form taught can be used individually or as a mixture of the two. The mixtures can be prepared by combining the desired quantities of the purified forms or the mixtures of the desired esters or salts thereof (Col 1, lines 5-15, 27-35, 39-47, Col. 3, Table 1, Col. 5, Example 4, Col. 6, Example 5 and 6, Claims 1-7).

Bruzzese also taught the use of these compositions for cardiovascular conditions and atherosclerosis, which encompasses varicose veins (see Mayo Clinic sheets scope of cardiovascular disease/conditions in the art) anticipating Claim 6 of the instant application.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Conclusion

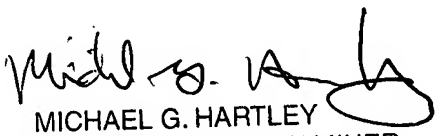
11. Claims 1-6 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Friday 7:30AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER

PTO/SB/08a/b (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/561,274
Filing Date	December 19, 2005
First Named Inventor	Toshihiko KAKIUCHI
Art Unit	N/A
Examiner Name	Not Yet Assigned
Attorney Docket Number	1110-0339PUS1

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
/GH/	CA	Nanzando, Igaku Daijiten (Gokaban), Dai 18 Han, Nanzando, (1998), p.981	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Gigi Huang/	Date Considered	05/15/2007